

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2022–N–1366 for “Data Standards; Requirement Begins for the Clinical Data Interchange Standards Consortium Versions 1.2 and 1.3 of the Analysis Data Model Implementation Guide.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT:

CDER: Helena Saviglin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1117, Silver Spring, MD 20993–0002, 240–402–6511, cderdatastandards@fda.hhs.gov.

CBER: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: FDA’s CBER and CDER are issuing this **Federal Register** notice to announce the date that support begins for versions 1.2 and 1.3 of the CDISC ADaMIG and the date that this version update is required in certain submissions. The FDA guidance for industry “Providing Regulatory Submissions in Electronic Format—Standardized Study Data” (June 2021) (eStudy Data guidance), posted on FDA’s Study Data Standards Resources web page at <https://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm>, implements the electronic submission requirements of section 745A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379k–1(a)) for study data contained in NDAs, ANDAs, certain BLAs, and certain INDs submitted to CDER or CBER by specifying the format for electronic submissions. The eStudy Data guidance states that a **Federal Register** notice will specify any new standards and version updates to FDA-supported study data standards that will be added to the Catalog, when the support for such standards and version updates begins or ends, and when the requirement to use such standards and version updates in submissions begins or ends.

Support for versions 1.2 and 1.3 of the CDISC ADaMIG begins July 18, 2022. The transition date for this version update is March 15, 2023. The requirement for electronic submissions to be submitted using versions 1.2 and 1.3 of the CDISC ADaMIG is March 15, 2024, for NDAs, ANDAs, certain BLAs, and certain INDs.

Dated: July 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–15248 Filed 7–15–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier OS–0990–0476]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment. This **Federal Register** notice seeks public comment on the revision recently submitted to OMB for review and approval. These comments will be reviewed and taken into consideration if the Department intends to make any revisions to the information collection request approved under [0990–0476]. Interested persons are invited to submit comments regarding the aforementioned non-substantive changes or any other aspect of this collection of information, including: the necessity and utility of the proposed information collection for the proper performance of the agency’s functions, the accuracy of the estimated burden, ways to enhance the quality, utility and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the ICR must be received on or before August 17, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice. To be assured consideration, comments and recommendations must be submitted www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, Sherrette.Funn@hhs.gov or (202) 264–0041. When submitting comments or requesting information, please include the document identifier 0990–0476–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information

collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: ASPA COVID-19 Public Education Campaign Market Research.

Type of Collection: Revision.

OMB No. 0990-0476—Office of the Assistant Secretary for Public Affairs (ASPA) within Office of the Secretary.

Abstract

The Office of the Assistant Secretary for Public Affairs (ASPA), U.S. Department of Health and Human Services (HHS) is requesting a revision on a currently approved collection including three components: 1. Current Events Tracker (CET), 2. Qualitative data collection in the form of focus groups, interviews, and dyads, and 3. Copy testing surveys. This revision supports continuation of the approved data collection by adding burden and iterations to support the program during

the ongoing COVID-19 public health emergency and through the expiration of the package 0990-0476 in early 2024. Together, these efforts support the development and execution of the COVID-19 Public Education Campaign. The broad purpose of each effort is as follows:

Current Events Tracker

The primary purpose of the COVID-19 Current Events Tracker (CET) survey is to continuously track key metrics of importance to the Campaign, including vaccine confidence and uptake, familiarity with and trust in HHS and other trusted messengers, and the impact of external events on key attitudes and behaviors. This information will inform Campaign development and execution including changes in messaging strategies necessary to effectively reach the entire U.S. population or specific subgroups.

Focus Groups/Interviews/Dyads

ASPA is collecting information qualitatively to inform the Campaign about audience risk knowledge, perceptions, current behaviors, and barriers and motivators to healthy

behaviors (including COVID-19 vaccination). Ultimately these focus groups, interviews, and/or dyads will provide in-depth insights regarding information needed by Campaign audiences as well as their attitudes and behaviors related to COVID-19 and the COVID-19 vaccines. These will be used to inform the development of Campaign messages and strategy.

Copy Testing Surveys

Prior to placing Campaign advertisements in market, ASPA will conduct copy testing surveys to ensure the final Campaign messages have the intended effect on target attitudes and behaviors. Copy testing surveys will be conducted with sample members who comprise the target audiences; these surveys will assess perceived effectiveness of the advertisements as well as the effect of exposure to an ad on key attitudes and behavioral intentions. The results from these surveys will be used internally by ASPA to inform decisions on Campaign messages and materials; for example, to identify revisions to the materials or determine which advertisement to move to market.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
CET	CET Questionnaire	^a 138,000	1	7.2/60	16,560
Foundational Focus Groups, Interviews, and/or Dyads ^b .	Screening and Interview	^c 50,000	1	9.3/60	7,750
Copy Testing Survey	Screening and Survey	^d 540,000	1	3.78/60	34,020
Sum of All Studies	728,000	58,330

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2022-15235 Filed 7-15-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C.,

as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neurobiology of Pain and Itch.

Date: July 29, 2022.

Time: 1:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: M. Catherine Bennett, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182,

MSC 7846, Bethesda, MD 20892, (301) 435-1766, bennettc3@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 13, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022-15283 Filed 7-15-22; 8:45 am]

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